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EXAMINER	
NAFF, DAVID M	
ART UNIT	PAPER NUMBER
1657	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/12/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/070,938	MORITA ET AL.	
	Examiner	Art Unit	
	David M. Naff	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-11 and 15-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-11 and 15-19* is/are rejected..

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

An amendment of 12/6/06, in response to an office action of 6/1/06, amended claim 7.

Claims examined on the merits are 7-11 and 15-19, which are all claims in the application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-11 and 15-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In line 6 of claim 7, "reinforcement being integrated with the sponge" is uncertain as to meaning and scope. The difference in structure when the reinforcement is integrated with the sponge as compared to when the reinforcement is not integrated with the sponge is uncertain. While the specification (page 8, lines 16-17) discloses that reinforcement is preferably integrated with the sponge, the specification fails to define the difference between being integrated and not integrated with the sponge.

Claim Rejections - 35 USC § 103

Claims 7-9, 11 and 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vacanti et al (5,855,610) in view of Vyakarnam et al (6,534,084) and Japanese patent (JP 3-23864) (Morita et al).

The claims are drawn to a method for regenerating cardiovascular tissue by seeding cells on a matrix comprising sponge configured to regenerate cardiovascular tissue and made of bioabsorbable material and a reinforcement made of a bioabsorbable material integrated with the sponge and located inside or on the exterior surface of the matrix, culturing the cells until the matrix surface is completely covered with cells, and embedding the matrix *in vivo* for generating cardiovascular tissue.

Vacanti et al disclose reconstruction and augmentation of flexible, strong connective tissue such as arteries and heart valves (col 1, lines 4-7). Objectives include producing tissue engineered constructs having improved mechanical strength and flexibility, making valves and vessels which can withstand repeated stress and strain, and improving yields of engineered tissues (col 2, lines 33-42). Structures are created by seeding a fibrous or porous polymeric matrix with cells (col 2, lines 65-67) to form tissues having structural elements such as heart valves and blood vessels (col 3, line 2-3). For a tissue to be constructed, successfully implanted and function, matrices must have sufficient surface area and exposure to nutrients such that cellular growth and differentiation can occur prior to the ingrowth of blood vessels following implantation (col 3, lines 26-29).

The matrix acts as a scaffold providing a three-dimensional space for cell growth. The matrix functions as a template providing structural cues for tissue development (col 3, lines 10-15). The scaffold determines the limits of tissue growth and thereby determines the ultimate shape of a tissue engineered construct. The cells on the matrix proliferate only to the edges of the matrix (col 3, lines 20-23). The matrix can be formed of polymers having a fibrous structure, which has sufficient interstitial spacing to allow for free diffusion of nutrients and gases to cells attached to the matrix surface. The spacing can be in a range of 100 to 300 microns, although closer spacings can be used if the matrix is implanted, blood vessels allowed to infiltrate the matrix, then the cells are seeded into the matrix (col 3, lines 42-49). The matrix can be sponge like (col 3, line 51), and can be a polyvinyl alcohol sponge (col 4, lines 25-27). The matrix can be formed of a biodegradable polymer such as poly(lactide) (PLA), poly(glycolic acid) (PGA) or poly(lactide-co-glycolide) (PLGA) (col 4, lines 8-11). Forms of lactic acid used to prepare PLA polymers can be L(+), D(-) or DL (col 4, lines 45-49). The overall matrix configuration is dependent on the tissue, which is to be constructed or augmented. The shape of the matrix can be obtained using struts that impart resistance to mechanical forces to yield the desired shape such as heart valve leaflets and tubes (col 3, lines 62-67, and col 5, lines 35-48). The struts can be biodegradable, and formed of the polymer material used to form the matrix to provide a matrix having sufficient strength to resist the necessary mechanical

forces. In Example 1 (beginning in col 7, line 60), a tissue engineered heart valve is produced. A PGA fiber based matrix is seeded with a mixed cell population containing myofibroblasts and endothelial cells and grown in culture until the myofibroblasts reached confluence. Then endothelial cells are seeded onto the surface of the fibroblast/mesh construct and grown into a single monolayer. The tissue engineered heart valve resembled native valve tissue. The construct was implanted in sheep to determine if the construct had the required pliability and mechanical strength (col 8, lines 21-23). In Example 2 (beginning in col 8, line 45), a tissue engineered vascular structure is prepared. A PGA tubular construct is seeded with a smooth muscle cells and fibroblasts. After the fibroblasts and smooth muscle cells have grown to confluence, endothelial cells are seeded on the construct and the construct placed in culture (col 8, lines 50-56). Endothelially lined smooth muscle/fibroblast tubes were created (col 9, lines 5-7). Vacanti et al disclose producing blood vessels, arteries and heart valves (cardiovascular tissue) using steps as claimed by seeding cells on a matrix made of bioabsorbable material configured to regenerate the tissue, culturing the cells on the matrix (Examples 1 and 2), and embedding the matrix *in vivo*, i.e. implanting the matrix containing tissue formed (col 2, lines 41-42, and col 8, line 21).

Vyakarnam et al disclose foam structures that can be composed of copolymers of lactide such as a poly(L) lactide-co-E-caprolactone (col 6, line 45, col 9, lines 53-55 and col 12, lines 5-9), and which can

be used to regenerate tissue such as tubular structures such as vascular grafts (col 3, lines 1 and 20-21, and col 9, lines 19-24). The pore size of the foam can be 30-50 Tm or 100-200 Tm (paragraph bridging cols 4 and 5). The foam can be reinforced with fibers (col 6, line 40) made of calcium phosphate.

The Japanese patent discloses a reinforced collagen sponge for implanting in tissue. The sponge is reinforced with fibers made of poly-L-lactic acid. See the translation (page 3, 4th paragraph). The sponge is used as a filler material embedded in a wound of defect to regenerate tissue (page 1 and paragraph bridging pages 1 and 2 of translation).

It would have been obvious to use a sponge as the matrix of Vacanti et al as suggested by Vyakarnam et al using foam structures that can be composed of copolymers of lactide such as a poly(L) lactide-co-E-caprolactone to regenerate tissue such as tubular structures such as vascular grafts, and the Japanese patent treating wounds and defects by using collagen sponge as a filler material embedded in damaged areas to regenerate tissue, and as suggested by Vacanti et al disclosing that the matrix used can be sponge-like (col 3, line 51) and using polyvinyl alcohol sponge as the matrix (col 4, lines 25-26). It would have been obvious to provide reinforcement of the sponge with a bioabsorbable material since Vacanti et al disclose that the matrix must have sufficient mechanical strength, and that the mechanical strength can be obtained by providing the matrix with

biodegradable struts to form a matrix having sufficient strength to resist mechanical forces. It would have been obvious to provide the reinforcement with fibers in the sponge as suggested by Vyakarnam et al using fibers in foam structures for reinforcement (col 6, line 40) and the Japanese patent using fibers inside a collagen sponge to maintain shape and strength (page 2 of translation). The fibers would have been expected to provide the shaping and strengthing function of the struts of Vacanti et al, and the fibers can be considered to be struts. Vacanti et al disclose that the struts can be implanted at the same time as the matrix (col 5, line 44), and having the fibers integrated with the matrix would have been obvious. Growing cells to confluence and forming a monolayer of endothelial cells on the matrix as in Example 1 of Vacanti et al (col 8, lines 12-15) will produce a matrix completely covered with cells as required in claim 7. Growing cells to confluence and culturing as in Example 2 of Vacanti et al will also result in the matrix completely covered with cells. Producing a blood vessel, as in claim 8 and a cardiac valve as in claim 9, is disclosed by Vacanti et al. In Examples 1 and 2, Vacanti et al use a mixed cell culture (col 8, lines 8, and 49-50) as in claim 11. Vacanti et al disclose using materials that are bioabsorbable (col 4, lines 9-15 and 41-49) as in claim 15. A pore diameter of 100 μm is encompassed by the pore diameter range of about 5 μm to about 100 μm of claim 19, and 100 μm would have been obvious from Vacanti et al disclosing the matrix containing interstitial spacing of 100 to 300 microns for diffusion of nutrients and gases to cells (col 3, line

46). As to claims 16-18, it would have been obvious to use polylactic acid or polyglycolic acid as the polymer forming the struts or fibers since Vacanti et al disclose these as biodegradable polymers that can be used to form the struts and sponge. It would have been further obvious to use lactic acid-caprolactone copolymer to form the sponge that can be the matrix of Vacanti et al since Vacanti et al disclose that the matrix can be formed of polylactic acid or poly(caprolactone) (col 4, lines 9-11), and Vyakarnam et al disclosing foam structures such as vascular grafts formed of poly(L) lactide-co-E-caprolactone for use in tissue engineering. The Japanese patent would have suggested reinforcement of a sponge with polylactic acid fibers.

Response to Arguments

Arguments in the amendment urge that the struts of Vacanti et al are entirely separate from the cell-matrix structure. However, Vacanti et al disclose that the struts and matrix can be implanted at the same time, and Vyakarnam et al and the Japanese patent disclose fibers in a foam or sponge for reinforcement. Having struts or fibers integrated with the matrix as to be part of the matrix of Vacanti et al seeded with cells would have been obvious to provide reinforcement. The disclosure of the struts pushing surrounding tissue by Vacanti et al is not disclosed by Vacanti et al to be a critical function of the struts. Vacanti et al disclose that the struts provide strength and shape to the matrix, and it would have been obvious to provide the struts or fibers as part of the matrix for these functions without pushing tissue.

The arguments urge that the examples of Vacanti et al do not disclose using struts, and the matrix of Vacanti et al after cell growth has sufficient strength. However, the struts disclosed by Vacanti et al are intended for use where the matrix does not have sufficient strength. The examples of Vacanti et al use a fiber-based matrix such as a PGA mesh (col 8, line 11), which has sufficient strength without the struts. Fibers in one part of the mesh apparently acted as a reinforcement for fibers in another part of the mesh. There is no description in the present specification to establish that the matrix in Example 1 not reinforced was a fiber mesh as disclosed by the examples of Vacanti et al. In Example 1 in the present specification, when the plain-weave cloth is omitted as reinforcement, there are no fibers present as contained by the fiber mesh of Vacanti et al. Obviously, the non-reinforced matrix used for comparison in Example 1 will not have the strength of the fiber mesh used in the examples of Vacanti et al. When using a non-fiber mesh matrix such as a sponge having less strength than the fiber mesh, it would have been obvious to provide reinforcement as suggested by Vacanti et al, Vyakarnam et al and the Japanese patent.

The arguments in the amendment urge that Vyakarnam et al suggest using reinforcing fibers only where higher stiffness is required. However, the matrix not reinforced in Example 1 in the present specification is less stiff than the sponge containing the plain-weave cloth. The stiffness disclosed by Vyakarnam et al provides the matrix

with greater strength, and would have been expected to make the matrix more resistant to rupture as occurs in Example 1.

The arguments urge that the Japanese patent does not seed the filler with cells, and that reinforcement is not needed after fully regenerated tissue is present. However, the sponge used to produce the regenerated tissue is reinforced with fibers to maintain strength and shape during production of the tissue, and after the tissue has been regenerated the sponge has been absorbed into the body. The present claims do not require the matrix to contain regenerated tissue, but instead require the matrix to be covered with cells before embedding in vivo. Since the matrix is bioabsorbable, the matrix will be absorbed into the body as disclosed by the Japanese patent when tissue is regenerated.

Claim Rejections - 35 USC § 103

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vacanti et al as applied to claims 7-9, 11 and 15-19 above, and further in view of Fofonoff et al (5,882,929) taken with Cox (6,719,789) or Love (5,509,930).

The claim requires pericardium tissue as the cardiovascular tissue regenerated.

Fofonoff et al disclose (col 20, lines 53-67) seeding a matt with cells to repair, reconstruct or replace tissue, which can be pericardial tissue (colo 20, line 66).

Cox discloses (col 24, lines 39-60) producing a heart valve using pericardium tissue.

Love discloses (col 1, lines 40-42, and col 10, lines 8 and 22) using pericardium tissue to produce a prosthetic heart valve.

When producing a heart valve by tissue engineering as disclosed by Vacanti et al, it would have been obvious to produce pericardium tissue to form the heart valve as suggested by Fofonoff et al producing pericardium tissue using a cell seeded matt, and Cox or Love using pericardium tissue to produce heart valves. Pericardium tissue would have been expected to be an effective tissue for producing a heart valve since this is a known tissue for producing a prosthetic heart valve.

Response to Arguments

Arguments in the amendment urge that Vacanti et al does not disclose or suggest reinforcement that is integrated with the sponge, and Fofonoff et al taken with Cox or Love do not suggest such reinforcement. However, for reasons set forth above, Vacanti et al, Vyakarnam et al and the Japanese patent suggest reinforcement integrated with the matrix. Fofonoff et al and Cox or Love are not relied on to suggest reinforcement.

Claim Rejections - 35 USC § 103

Claims 7, 8 and 11 are are rejected under 35 U.S.C. 103(a) as being unpatentable over Naughton et al (5,863,531).

The claimed invention is described above.

Naughton et al disclose producing tissue *in vitro* by seeding cells on a three-dimensional framework having interstitial spaces, which can be shaped to assume the conformation of natural organs and

their components (col 4, lines 63-64). The three-dimensional framework can be formed of biodegradable matrices such as collagen sponge (col 9, line 42), or polyglycolic acid or polylactic acid and copolymers thereof (col 9, lines 59-62). Tubular tissue structures can be formed (col 6, lines 55-60 and col 22, line 41) such as in the form of blood vessels (col 24, line 33), arteries (col 24, line 37) or veins (col 25, line 24). Implantation of a valve is also disclosed (col 19, line 49). Stromal cells such as fibroblasts or stromal cells in combination with other cells such as endothelial cells or smooth muscle cells (col 4, lines 23-28, and col 11, lines 9-25) are grown *in vitro* on the framework where the stromal cells and their naturally secreted extracellular matrix proteins and connective tissue proteins envelop the framework to form a three dimensional living stromal tissue (col 4, lines 30-44, col 7, lines 51-60, and col 11, line 64). Since the inner walls of arteries are rich in elastin, an arterial stroma should contain a high concentration of smooth muscle cells which elaborate elastin (col 13, lines 28-31). The elastin provides strength and elasticity required of blood vessels *in vivo* (col 4, lines 2-9). Once the three dimensional tissue has reached the appropriate degree of growth, tissue-specific cells are inoculated on the stromal tissue, and can be grown on the stromal tissue *in vitro* to form a cultured counterpart of the native tissue prior to implantation *in vivo* (paragraph bridging cols 13 and 14, and col 14, lines 5-10). The cells chosen for inoculation depend on the tissue to be produced such as epithelium, endothelium and smooth muscle (col 14, lines 13-

16). When producing arties, fibroblast cells and smooth muscle cells can be cultured to subconfluence on separate frameworks, the frameworks combined and the smooth muscle cells proliferated to produce elastin to simulate natural arterial walls. Thereafter, endothelial cells are seeded on top of an upper, elastin-rich layer, and incubated until they form a confluent layer (paragraph bridging cols 24 and 25, and col 25, lines 11-15).

When producing tubular tissue structures such are arteries, veins, blood vessels that are cardiovascular tissue as disclosed by Naughton et al, it would have been obvious to use collagen sponge as the framework in which cells are cultured to produce the tissue as suggested by Naughton et al (col 9, line 60). The collagen sponge is a sponge matrix as required by the present claims, and the method disclosed by Naughton et al when using collagen sponge is the same presently claimed. The extracellular matrix containing elastin produced during culturing stromal cells will result in the extracellular matrix being integrated with the matrix and functioning for reinforcement prior to seeding the matrix with tissue specific cells. Naughton et al disclose that elastin is a necessary component of blood vessels and provides strength (col 4, line 5) to the vessels, and is normal component of arteries (col 13, lines 28-31). After culturing tissue-specific cells on the stromal tissue contained by the collagen sponge, the sponge surface will be completely covered with cells since Naughton et al disclose that the tissue produced is a counterpart of native tissue prior to implantation (col 14, lines 7-

10), and disclose culturing seeded endothelial cells on a elastin-rich layer to form a confluent layer (col 25, lines 13-15). A collagen sponge that is not completely covered with tissue formed by culturing the tissue-specific cells will not be a counterpart of native tissue. Naughton et al suggest a blood vessel (col 24, line 33) as required by claim 8, and a mixed cell culture (col 8, lines 16-17, and col 11, lines 9-15) as required by claim 11.

Response to Arguments

Arguments in the amendment urge that Naughton et al do not teach a fibrous reinforcing material integrated with the sponge. However, claim 7 does requirement a "fibrous reinforcing material". The reinforcing material can be any material capable of reinforcing. The extracellular matrix containing elastin produced during culturing stromal cells as disclosed by Naughton et al will be inside and/or on the surface of the sponge, and will be integrated with the matrix before the matrix is seeded with tissue specific cells. The present claims do not exclude the reinforced matrix before seeding with cells being a matrix previously used to culture stromal cells as disclosed by Naughton et al. Additionally, the claims do not specify how the reinforcement is integrated with the matrix. The claims encompass the reinforcement being integrated with the matrix by producing the reinforcement in the matrix during a step of cell culture before seeding followed by culturing tissue specific cells on the matrix as disclosed by Naughton el al. The extracellular matrix of Naughton et

al is integrated with the matrix before the tissue specific cells are added to the matrix.

Claim Rejections - 35 USC § 103

Claim 9, 15 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Naughton et al as applied to claims 7, 8 and 11 above, and further in view of Vacanti et al.

The claimed invention, Naughton et al and Vacanti et al are described above.

It would have been obvious to use the procedure of Naughton et al to produce a heart valve as in claim 9 in view of Vacanti et al producing vascular structures or heart valves by a procedure similar to that of Naughton et al. Using bioabsorbable materials of claim 15 to produce a sponge instead of from collagen and to produce a reinforcement in addition to extracellular matrix containing elastin in Naughton et al would have been suggested by Vacanti et al using such materials to produce a biodegradable sponge-like matrix and a biodegradable reinforcement (struts) in a procedure similar to that of Naughton et al. Since Vacanti et al can use smooth muscle cells that produce elastin (col 8, line 50) and use struts for reinforcement, it would have been apparent that reinforcement such as struts can be desirable even when elastin is present. A pore size in the range of claim 19 would been obvious from Vacanti et al disclosing spacings of 100 to 300 microns (col 3, line 46).

Response to Arguments

The arguments urge that Naughton et al and Vacanti et al do not disclose reinforcement integrated with the sponge, and located inside or on the exterior surface of the matrix. However, for reasons set forth above, Naughton et al suggest reinforcement integrated with the sponge.

Claim Rejections - 35 USC § 103

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 9 and 15 above, and further in view of Fofonoff et al taken with Cox or Love.

The claimed invention and references are described above.

When producing a heart valve by the procedure of Naughton et al as suggested by Vacanti et al as set forth above, it would have been obvious to produce pericardium tissue to form the heart valve as suggested by Fofonoff et al producing pericardium tissue using a cell seeded matt, and Cox or Love using pericardium tissue to produce a heart valve. Pericardium tissue would have been expected to be an effective tissue for producing a heart valve since this is a known tissue for producing a prosthetic heart valve.

Response to Arguments

The type of response to arguments set forth above in regard to claims 9, 15 and 19 also applies to arguments traversing this rejection.

Claim Rejections - 35 USC § 103

Claims 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 9, 15 and 19 above, and further in view of Vyakarnam et al, and if necessary in further view of the Japanese patant.

The invention and references described above.

When modifying Naughton et al as suggested by Vacanti et al as set forth above, it would have been obvious to use polylactic acid or polyglycolic acid as the polymer forming the struts since Vacanti et al disclose these as biodegradable polymers that can be used to form the struts and sponge. It would have been further obvious to use lactic acid-caprolactone copolymer to form the sponge that can be the framework of Naughton et al as suggested by Vacanti et al since Vacanti et al disclose that the matrix can be formed of polylactic acid or poly(caprolactone) (col 4, lines 9-11), and Vyakarnam et al disclose foam structures such as vascular grafts formed of poly(L) lactide-co-E-caprolactone for use in tissue engineering. If needed, the Japanese patent would have suggested reinforcement of a sponge with polylactic acid fibers.

Response to Arguments

The type of response to arguments set forth above in regard to claims 9, 15 and 19 also applies to arguments traversing this rejection.

Bell et al (4,546,500) is made of record to further show reinforcement of engineered vessels.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David M. Naff
Primary Examiner
Art Unit 1657

DMN
3/5/07